Safety Data Sheet

Product: **Cetirizine Hydrochloride**

Effective Date: 09/01/2021

Prepared By	Checked By	Approved By
EHS 09/01/21	Head - R&D 09/01/21	Head- QA 09/01/21

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identification

Trade name: Cetirizine (Hydrochloride)

Synonym: 2-[2-[4-[(4-chlorophenyl) phenyl methyl]-1-piperazinyl] ethoxy]-acetic acid dihydrochloride.

CAS Number: 83881-52-1

EC number: 620-533-8

1.2 Relevant identified uses of the substance or mixture and uses advised against.

Identified uses: Laboratory chemicals, Manufacture of substances.

1.3 Details of the supplier of the safety data sheet

Company : Supriya Lifescience Limited.
A-5/2, Lote Parshuram M.I.D.C.
Industrial Area
Tal. - Khed, Dist. – Ratnagiri.

1.4 Emergency Telephone Number

Tel. No.: 91-2356-272299

Chemical Formula: $C_{21}H_{25}ClN_2O_3.2HCl$

Fax No.: 91-2356-272178

E-mail id: supriya@supriyalifescience.com

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Acute Tox. 4 H302 Harmful if swallowed.

Label elements

2.2 GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms

GHS07

Signal word Warning

Hazard statements

Harmful if swallowed.

Precautionary statements

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

If swallowed: Call a poison center/doctor if you feel unwell.

Rinse mouth.

Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)

Health = 2, Fire = 0, Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 2, Fire = 0, Reactivity = 0

2.3. Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

3.1 Chemical characterization: Substances

CAS No. Description

83881-52-1 Cetirizine (hydrochloride)

Component	Classification	Concentration
Cetirizine Hydrochloride	Acute Tox. 4; H302	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

Section 4: First Aid Measures

4.1 Description of first aid measures

General information: Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhalation: Supply fresh air; consult doctor in case of complaints.

In case of skin contact: Wash off with soap and plenty of water. Consult a physician.

If case of eye contact: Rinse opened eye for several minutes under running water.

If swallowing: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed :

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

Use fire fighting measures that suit the environment.

A solid water stream may be inefficient.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 **Advice for fire-fighters**

Protective equipment: No special measures required.

Section 6: Accidental Release Measures

6.1 **Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

6.2 **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

6.3 **Methods and material for containment and cleaning up:**

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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Section 7: Handling and Storage

7.1 Handling:

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust

Ventilation at places where dust is formed. For precautions see section 2.2.

7.2 **Conditions for safe storage, including any incompatibilities**

BP/Ph.Eur.: Store protected from light.

IP : Store protected from light.

USP: Preserve in tight containers, protected from light and moisture. Store at room temperature.

7.3 **Specific end use(s)** No further relevant information available.

Section 8: Exposure Controls/Personal Protection

8.1 Additional information about design of technical systems: No further data; see item 7.

Control parameters: Components with workplace control parameters

8.2 **Exposure controls**

Personal protective equipment:

General protective and hygienic measures: Wash hands before breaks and at the end of work.

Breathing equipment: Not required.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Safety glasses with side-shields

Section 9: Physical and Chemical Properties

9.1 **Information on basic physical and chemical properties**

General Information

Appearance : White powder

Form : Crystalline

Color : Not determined.

Odor : Characteristic

Structural Formula : $C_{21}H_{25}ClN_2O_3$. 2HCl

Molecular Weight : 461.8 g/mol

Odor threshold : Not determined.

pH-value : Not applicable.

Change in condition

Melting point/Melting range: 110- 115° C

Boiling point/Boiling range: Undetermined.

Flash point: Not applicable.

Flammability (solid, gaseous): Product is not flammable.

Decomposition temperature: Not determined.

Auto igniting: Not determined.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapour pressure: Not applicable.

Density: Not determined.

Relative density: Not determined.

Vapour density: Not applicable.

Evaporation rate: Not applicable.

Solubility in / Miscibility with

Water: Water soluble

Partition coefficient (n-octanol/water): Not determined.

Viscosity:

Dynamic: Not applicable.

Kinematic: Not applicable.

SOLUBILITY ~10 mg/ml in PBS (pH 7.2); ~12 mg/ml in DMSO; ~3 mg/ml in DMF

9.2 **Other information:** No further relevant information available.

Section 10: Stability and Reactivity Data

10.1 **Reactivity:** No further relevant information available.

10.2 **Chemical stability**

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 **Possibility of hazardous reactions:** No dangerous reactions known.

10.4 **Conditions to avoid:** No further relevant information available.

10.5 **Incompatible materials:** strong oxidizing agents.

10.6 **Hazardous decomposition products:** carbon oxides, hydrogen chloride, nitrogen oxides.

Section 11: Toxicological Information

11.1 **Information on toxicological effects**

Acute toxicity:

LD/LC50 values that are relevant for classification:

Oral	LD50	365 mg/kg (rat)
	TDLO	0.1 mg/kg (mouse)
	Interperitoneal LDLO	138 mg/kg (mouse)

Primary irritant effect:

on the skin: No irritant effect.

on the eye: No irritating effect.

Sensitization: No sensitizing effects known.

Additional toxicological information:

Carcinogenic categories

IARC (International Agency for Research on Cancer) Substance is not listed.

NTP (National Toxicology Program) Substance is not listed.

OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

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Section 12: Ecological Information

12.1 **Toxicity**

Aquatic toxicity: No further relevant information available.

Persistence and degradability: No further relevant information available.

Behavior in environmental systems:

Bioaccumulative potential : No further relevant information available.

Mobility in soil No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Other adverse effects No further relevant information available.

Section 13: Disposal Considerations

13.1 **Waste treatment methods**

Recommendation:

Must not be disposed of together with household garbage.

Do not allow product to reach sewage system.

Un cleaned packaging :

Recommendation: Disposal must be made according to official regulations.

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Section 14: Transport Information

14.1 **UN-Number**

DOT, IMDG, IATA : Not regulated
UN proper shipping name:
DOT, IMDG, IATA: Not regulated
Transport hazard class(es) :
DOT, ADN, IMDG, IATA:
Class: Not regulated
Packing group:
DOT, IMDG, IATA: Not regulated
Environmental hazards: Not applicable.
Special precautions for user: Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code : Not applicable.
UN "Model Regulation" : Not regulated

Section 15: Other Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance

Section 355 (extremely hazardous substances): Substance is not listed.

Section 313 (Specific toxic chemical listings): Substance is not listed.

TSCA (Toxic Substances Control Act): Substance is not listed.

Hazardous Air Pollutants: Substance is not listed.

Proposition 65

Chemicals known to cause cancer: Substance is not listed.

Chemicals known to cause reproductive toxicity for females: Substance is not listed.

Chemicals known to cause reproductive toxicity for males: Substance is not listed.

Chemicals known to cause developmental toxicity: Substance is not listed.

Carcinogenic categories

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EPA (Environmental Protection Agency) Substance is not listed.

TLV (Threshold Limit Value established by ACGIH) Substance is not listed.

NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.

GHS label elements

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

Section 16: Other Information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing SDS: Environment protection department.

Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative